

## 510(k) Summary

**5. K124045 Summary (Updated July 9, 2013)****JUL 10 2013**

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared:	December 28, 2012	Revised July 9, 2013
Applicant:	Solana Surgical, LLC	Contact: Joe Clift
	6363 Poplar Ave, Suite 312	(901) 818-1860
	Memphis, TN 38119	

<b>Common Name:</b>	Staple, Fixation, Bone
<b>Device Trade Name:</b>	FuseForce Implant System
<b>Device Classification Name:</b>	Single/Multiple component metallic bone fixation appliances and accessories
<b>Device Classification:</b>	Class II
<b>Reviewing Panel:</b>	Orthopedic
<b>Regulation Number:</b>	21 CFR 888.3030
<b>Product Code:</b>	JDR
<b>Predicate Device:</b>	K070031 Memometal Memory Staples

**Device Description:**

The Solana Surgical FuseForce Implant is a one-piece device made of Nickel Titanium Alloy intended to be implanted in the bones of the hand or foot. The implant is available in a range of sizes (12) ranging from 8 mm X 8 mm to 25 mm X 22 mm including both straight top and step top configurations. The design of the Solana Surgical implant is similar to the predicate device. No new materials or processes are used in the production of this implant. The device is provided in a sterile package which includes associated single use (disposable) instruments.

**Indications for Use:**

The Solana Surgical, LLC FuseForce Implant System is intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as: LisFranc arthrodesis, Akin Osteotomy, Scarf and Chevron osteotomies

**Summary Comparison to Predicate Devices:**

Similarities of the Solana Surgical device to its predicates include these devices being intended for single use only and for surgical implantation longer than 30 days. The Solana Surgical device and the predicate device have similar design characteristics and intended use. The stated indications for use add specificity to that of the predicate by listing examples of procedures within the broader context of the predicate's statement. The indications for use of the subject device are, therefore, not new but merely better defined. Comparative bench testing per ASTM F564 indicates that the subject staple performance exceeds that of the predicate device in all cases evaluated. Original mechanical testing was performed at room temperature. Additional mechanical testing at body temperature was performed to characterize the performance of the subject device and a legally marketed predicate, the Memometal EasyClip staple.

The devices tested were 8mm x 8mm x 8mm nitinol staples which represent the worst-case for 1.) pullout fixation strength, 2.) static bending and 3.) fatigue bending. For both devices, production components were used. Six subject devices and six predicate devices were evaluated in each test. See Attachment K "VR-029 - "Staple Mechanical Testing Report - FuseForce Implant System".

The Solana subject device exceeded or was equivalent to the predicate in mechanical performance and therefore demonstrates acceptable mechanical characteristics.

Comparative testing characterized the corrosion resistance of the subject device and a legally marketed predicate, the Memometal EasyClip staple. The testing was performed per ASTM F 2129. The devices tested were 25mm x 22mm x 22mm nitinol staples which represent the largest surface area and, therefore, worst case for corrosion susceptibility. For both devices, production components were used and a simulated implantation in bone substitute was performed. Six subject devices and six predicate devices were tested. See Attachment J "VR-026 - Staple Implant Corrosion Validation".

The subject device demonstrates a breakdown potential (Eb) that is higher than that of the predicate suggesting that the subject device exhibits an acceptable level of corrosion resistance.

The subject device is substantially equivalent to the predicates devices and should not introduce new concerns in terms of safety or effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

July 10, 2013

Solana Surgical, LLC  
% Mr. Joe Clift  
Senior Vice President Technical Operations and Compliance  
6363 Poplar Avenue, Suite 312  
Memphis, Tennessee 38119

Re: K124045

Trade/Device Name: FuseForce Implant System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: Class II

Product Code: JDR

Dated: May 29, 2013

Received: June 03, 2013

Dear Mr. Clift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

Page 2 – Mr. Joe Clift

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Erin Keith**

For

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K124045  
Device Name: FuseForce Implant System  
Indications for Use:

The Solana Surgical, LLC FuseForce Implant System is intended to provide fixation for fractures, fusions or osteotomies of the bones of the hand and foot such as: LisFranc arthrodesis, Akin Osteotomy, Scarf and Chevron osteotomies

Prescription Use   X   AND/OR Over-The-Counter Use             
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)  
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.  
Division of Orthopedic Devices